Manual

FOX

Medical Diode Laser System

810 nm, 980 nm, 1064 nm

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CE 1275

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FOX Laser

The multi-functional diode laser with green aiming beam,
touch screen and programmable power

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1 Introduction

We appreciate your decision to purchase the FOX Laser and wishing you a productive and successful usage with this multi-functional laser system.

The FOX Laser generates high-intensity laser beam which may induce injuries in improper handling. Therefore, this User Manual should be read carefully before using the device. Should you have any further questions regarding safety, the use of the device, or concerning laser and laser radiation, please contact A.R.C. Laser GmbH or your local authorized dealer (see Section 10.3 "Sales and Service - Information").

A T T E N T I O N !
We are obliged by local laws to sell this device only to licensed physicians, through our local authorized dealer which holds a valid Canadian MDEL (Medical Device Establishment Licence).

1.1 Copyright

This user manual is protected under copyright. The copyright prohibit any duplication of parts or of the entire user manual without an explicit written consent by A.R.C. Laser GmbH.

Approved copy or parts extracted from this user manual, as licensed by A.R.C. Laser GmbH, shall include references to the original document and author as stated in this original document. Furthermore, this copyright applies to any translated copy of the user manual to other languages.

We would like to point out that this user manual was prepared based on A.R.C. Laser proprietary data and to the best of our knowledge. A.R.C. Laser reserve the rights to revise, renew or modify any of the included drawings, images or text without further notice. In case of any content change, the revised document will be readily available for the regulatory authorities.

1.2 Marking and Symbols

The international sign **"Attention"** is mounted on all surfaces, which are hazardous for the user. Before carrying out any further works at such marked parts, please read the user manual or contact your local dealer or contact directly to A.R.C. Laser GmbH service department.

The laser radiation sign is intended to warn the user against aiming laser beams to undesired surfaces by improper handling. The laser beams of this device are not visible. When using the protection goggles filtering such beams, the user can neither identify nor see the beams.

1.3 Intended Use

The FOX Laser is intended to be used for treatments requiring heating of tissue and/or blood up to coagulation or vaporization). At high power outputs, tissue can be carbonized, removed or separated by vaporization.

At low power output, heating of tissue or blood results in enzyme denaturation and coagulation of blood vessels.

To this effect, the laser is used together with application fibers aiming the laser beam to the target tissue either directly or via further optics (e.g. through hand pieces other illustrating optics).

The laser effect has been designed to allow focused treatment of the disease area with minimal impact on the surrounding tissue. Therefore, selecting the right laser parameters are essential to allow minimal pain, avoid injuries and achieve maximum results.

Using the laser in any and all other treatment methods is far superior in terms of traumatization and efficiency and the laser treatment is part of the innovative treatment methods in modern surgery.

The laser can be applied both in unsterile environment, for instance at a physician examination room, and in a sterile operating room.

CAUTION – The device may only be used by physicians that undergone appropriate training and have extent knowledge of the medical effects and risks involved in using this device, as well as the understanding for using this device in accordance with this manual.
Laser equipment not in use should always be protected against unqualified use.

2 Theory and Technical Background of a Diode Laser

This laser is a mere diode laser with a laser diode as the beam source. The laser diode can radiate light in the range of various wavelengths. The FOX Laser can be supplied with the wavelengths of 810 nm, 980 nm or 1064 nm. The laser radiation of the diode is collimated through the optics in the „fast“ and in the „slow“ axis and consequently transferred to a surface of approx. 2mm x 4mm.

The word laser means „light amplification by stimulated emission of radiation“.

All laser types include three fundamental elements:

The **lasing medium** (providing atoms), or molecules allowing to amplify the light.

An **excitation source** (the abovementioned molecules or atoms are excited with), and an optical **resonator** which, similar to a resonant circuit, supports or generates the radiation stimulated by the internal reflection.

Atoms and molecules may have different energy states, which can generate electromagnetic phosound radiation changing from one state to the next by means of absorption and consequently by radiation. In their normal state, the electrons of an atom are in the so-called basic or normal state.

By supplying energy through light – or though plasma formation, as noble gas lasers do – electrons are transported into the higher state. The dwell time in the higher state is very short though. and the electrons sink back into their original state. During this short phase, the previously stored energy is released again by sending out photons.

The consequently emitting photons have the same wavelength and the same direction within the laser. Inside the resonator cavity, the photons between the two mirrors are compelled to pass through the cavity several times. During this time, they hit further photons thus generating a monochromatic light. To make the light built up this way in the resonator also accessible outside, the initial mirror of the laser is made permeable in parallel.

The laser diode is operated with high current up to 20 amperes and low voltage. Since the diode is very sensitive to any voltage fluctuations, the battery integrated into the FOX Laser has a buffer preventing any voltage fluctuations at the diode. Doping the individual junctions as well as the individual production processes allows A.R.C. Laser to provide the laser diodes in these wavelengths.

The power output varies per individual wavelengths. Through PN junctions, only certain layer thicknesses can be reached, and consequently only certain wavelengths can be generated.

The current running through the laser diode is generated by current drivers in the electronic system thus allowing the user to control the output power through the touch screen display.

Via beam deflection mirrors and coupling ceramic elements the laser light is coupled into a silica glass fiber. The transmission of the various wavelengths is independent from the fiber. Transmissions ranging from 70 to 80 % of the laser power are possible.

The laser diode is controlled by internal electronic system that is adjustable through the device control monitor. The FOX laser output power as well as pulse length and pulse width can be controlled individually.

The laser beam emitted from the diode is polarized and therefore easy to ramp up or down. By means of direct cooling, the diode gets the specified temperature which kept stable. The

cooling circuit is passive and control the internal fans, to allow natural or forced convection heat dissipation, depending on the load.

3 Transport and Storage

The FOX Laser is supplied in a custom made carrying case for ultimate protection during transportation. Accessories such as fibers and hand pieces are fully protected as well, as they have dedicated spaces within the carrying case and can transported together with the laser console.

For deliveries by mail, the carrying case is protected by a special outer cardboard box. The carrying case is designed to ensure the user can perfectly stow and transport the FOX Laser when changing rooms and/or site location.

The device should never be exposed to temperatures below 2°C. or above 40°C The ambient air must be dry and clean. Ambient air humidity exceeding 80% may result in diode layers burning down when switching on the device.

The FOX Laser should be transported and stored only in its original carrying case to avoid damage.

A T T E N T I O N!
The FOX Laser should be protected against water and moisture!

4 Installation

4.1 Installation Site

Usually, the Fox Laser is installed by A.R.C. Laser GmbH or its authorized dealer, and you will be given full training for the device. Prior to delivery, however, the user need to make sure a suitable location was prepared for the installation.

The FOX Laser should be installed at a readily accessible place not too close to a heater or next to a sink. The laser should not be operated close to a heater as its air cooling system works best when the ambient temperature does not exceed 21°C.

Higher ambient temperature may result in shorter working times as the device will be switching off earlier to prevent overheating.

If the ambient temperature is too low (below 10°C), the device cannot be started, in order to avoid possible condensation on its internal optics as this might cause a permanent damage.

All control elements need to be readily accessible. The fibers at the front must have sufficient space to avoid accidental bending. The air humidity in the treatment room should be monitored and kept below 75%.

4.2 Room Requirements

Legislation imposes the following requirements to any room in which a class 4 laser (according to EN 60825-1) is operated.

4.2.1 Warning signs

All ingresses shall be clearly marked to prevent an outside person from entering as this might be hazardous.

- Please attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- Please mount a warning lamp above each access door which always has to light up, when the laser is in operation.
  This ensures warning to prevent accidental entry to the room without protective goggles.
- Please store the laser protective goggles at the entrance of the room and make sure they are readily accessible.

4.2.2 Windows shielding

Windows need to be covered with suitable masking or shielding to prevent laser radiation leakage. For any question or in case of any doubt, please contact your local A.R.C. Laser authorized dealer, or contact directly to A.R.C. Laser GmbH at any time.

4.2.3 Reflecting surfaces

To avoid possible danger caused by reflected radiation direct or scattered, reflecting surfaces must not be present in the room during operation. Such surfaces may include

- mirrors
- pictures with front glass
- chrome surfaces
- windows

These surfaces must be either removed or covered with suitable matt type material. Even at the area around the laser fiber port, use only matted, non-reflecting as well as non-combustible instruments and materials.

4.3 Electrical Connection

The laser is operated with a DC voltage of 19 V, supplied by its internal battery pack and charged by an external power supply unit. The internal battery pack is developed by A.R.C. Laser specifically for this device. Only use battery packs and power supplies made by A.R.C. Laser GmbH and obtained through the authorized dealer.

The power supply unit can be connected to a AC voltage ranging from 100V to 240V at 50Hz-60Hz. Specifications are as labeled.

4.4 Battery pack

If the battery pack is mishandled, the battery pack can burst, cause a fire or even chemical burns. Observe the following cautions.

- Do not disassemble. Do not handle damaged or leaking lithium ion batteries.
- Do not crush and do not expose the battery pack to any shock or force such as hammering, dropping or stepping on it.
- Do not short circuit and do not allow metal objects to come into contact with the battery terminals.
- Do not expose to high temperature above 60°C (140°F) such as indirect sunlight or place located in the sun.
- Do not incinerate or dispose of in fire.

Disposal of waste batteries (applicable in the European Union and other European countries with separate collection systems)

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste.

In case of products that for safety, performance or data integrity reasons require a permanent connection with an incorporated battery, this battery should be replaced by qualified service staff only. To ensure that the battery will be treated properly, hand over the product at end-of-life to the applicable collection point for the recycling of electrical and electronic equipment.

5 Safety Information and Technical Acceptance

5.1 General

The FOX Laser is a precision instrument for medical applications. A.R.C. Laser has devoted the utmost care for safety aspects during its design and manufacturing as well as implementing intensive testing procedures prior shipment, to ensure the device you are receiving is safe to use.

Following the "*Radiation Emitting Devices Act* " of your Country, it is highly advisable to keep with the device, detailed laser safety instructions and inform the person using the device on their location.

FOX laser devices are classified according to EN 60601-2-22 and EN 60825-1, as a ***Class 4 Laser Product***.

As such, to ensure that individuals are not exposed to direct, reflected or scattered laser radiation without appropriate protection, it is necessary prior usage to:

- Create a "*laser treatment controlled area*" within the facility
- Post appropriate laser warning signs at the entry way to the laser controlled area
- Use a door, blocking barrier, screen, or curtains to attenuate laser radiation in the entryway

(A laser treatment controlled area is simply an area that is appropriately enclosed so that laser radiation which is above the maximum permissible exposure (MPE) does not inadvertently escape the treatment area to injure unsuspecting persons).

Additionally, during laser usage it is necessary to:

- Be under the direct control of authorized laser personnel trained in laser safety and laser operation;
- Have only diffusely reflecting materials in or near the beam path (i.e. reflective items such as mirrors or jewelry must be removed or covered);
- Provide personnel and patients with appropriate eye protection;
- Have high background illumination;
- Have all accessible windows, doorways, etc. covered;
- Have room walls that are rough in texture, dark and non-reflecting;
- Have limited amounts of flammable compounds or substances;
- Provide adequate ventilation, respirators, firefighting equipment, etc. to control all laser hazards;

According to ***Class 4 Laser Product*** regulations, the FOX Laser is equipped with:

- A secure storage and a power-off switch for the laser when not in use to prevent unauthorized operation.

- A large visible Red “Stop” button for deactivating the laser in the event of an emergency; Audible and visible activation warning system to indicate that the laser is in ready mode and operation;
- A master switch to control patient exposure;
- A door interlock switch, which is an interlock plug switch that can be connected to the door. When the door is opened, the device will immediately switch off; however, we also recommend to manually lock the door from the inside to prevent unintentional entry.

Even though the safety information included in this manual is detailed, it is not intend to replace industry standards and guidelines for laser safety.

We would recommend keeping the document “*Operation of Laser Facilities and Accident Prevention Regulations for Laser Radiation*” which may be obtained through your local authorized dealer.

In addition, you can refer to the regulations of the American National Standard Agency ANSI Z136.3-1996 "*American National Standard for the Safe Use of Lasers in Health Care Facilities*" and ANSI Z136.1-1995 "*American National Standard for the Use of Lasers*“.

Our local dealer's technical support department will gladly answer any questions you may have and provide you with appropriate training as well as assist with obtaining additional industry standards and guidelines for laser safety.

5.2 Eyewear protection

A T T E N T I O N!
Never look directly into the laser beam or to the light reflected by the laser beam. Never look directly into the exit of the fiber optics or into the exit of a laser optics (e.g. hand piece) as this will cause serious eye injury.

⇒ Eyewear (safety goggles) is the single most important piece of protective equipment needed by persons within the laser treatment controlled area.

Protective eyewear for both the operator and the patient needs to be able to stop laser radiation coming from all directions from striking the eye.

This means the eyewear must have side and top guards and fit snugly around the nose. Laser protective eyewear for the laser operator must also allow visible light to pass through it so that the wearer can see adequately to perform their tasks safely, while at the same time preventing the wavelength emitted by the laser from passing through.

⇒ The most important factor for protective eyewear is that it must protect against the specific wavelength emitted by the laser.
Therefore, use only goggles labeled with the same wavelength as the model of FOX Laser you are about to use (810 nm or 980 nm or 1064 nm).

NOTE: Eyewear will NOT provide protection for lasers that emit radiation of a different wavelength from that which the eyewear is designed for. Simple safety goggles or glasses must NEVER be used for laser eye protection!

⇒ The second important factor is the optical density number, which defines how much of the laser radiation is reduced when it passes through the protective eyewear.
For all Fox models, use laser safety goggles with either protection class (OD 7+), or protection class (DL5+DIRL5).

Your FOX Laser package is supplied with two units of laser safety goggles, according to the wavelength model, intended to be wear directly (i.e. not to be wear on top of glasses).

Protective goggles that meet all safety requirements can be obtained through your local A.R.C. Laser authorized dealer, including special models someone can wear on top of glasses.

- Keep laser eyewear in an opaque case when it is not in use, as the coating can be degraded by exposure to daylight over time
- Follow the laser eyewear manufacturer's recommendations on shelf life, storage conditions and appropriate cleaning methods.
- Inspect protective eyewear regularly. In case you suspected of any physical damage (cracks, dents, scratches, discoloration, layers peeling), DO NOT use; please contact your local A.R.C. Laser authorized dealer for replacement.

Should you require any additional information on protective goggles, please contact your local A.R.C. Laser authorized dealer.

5.3 Electrical Protection

The FOX Laser works with a low internal voltage of 19 V. Do not disassemble the unit. Never remove any housing parts as this can cause a serious risk hazard as it may immediately destroy the laser diodes.

Any service to the unit or its accessories should only be carried out by an authorized personnel by A.R.C. Laser GmbH.

The room in which the laser is operated should be kept dry. For room that needs to be cleaned with the use of water, please make sure the floor has dried out before using the laser.

A T T E N T I O N!
Never work with the device if you notice any visible damage to the console or to the accessories.

A T T E N T I O N!
Never work with the device if you notice any visible damage to outlet plug, or notice the wires have become exposed as a consequence of improper handling.

The FOX Laser should undergo a safety inspection every 24 months, carried out by qualified personnel.

5.4 Explosion and Fire Hazard

A T T E N T I O N!
Never work with the laser in the vicinity of easily flammable anesthetics, easily flammable solutions or material. In particular, please remove combustible plastic or paper elements from and around the working area of the laser. Focusing the green or IR laser beam on flammable materials may ignite these and cause a fire or expulsion!

When working with the laser, make sure the laser is switched from READY mode to STAND-BY mode, in case the treatment has to be interrupted. This will assure that no laser radiation will be emitted due to unintentional stepping on the pedal switch.

5.5 Protection against Undesired Radiation

Never grip the hand piece or fiber tip with their exit pointing or touching your exposed skin as this may cause burns to the skin; do not focus the laser beam on easily flammable materials as this may cause a fire.

The pedal switch controlling the laser pulse should never be outside the range of the operator holding the laser hand piece/fiber. It is prohibited that any person other than the operator controls the pedal switch.

In operating rooms in which several pedal switches are available, it is particularly important to make sure that the laser pedal switch is in within the operator vicinity and recommended to be clearly marked as the FOX Laser pedal switch.

A T T E N T I O N !
During a laser treatment, the system is in "Ready" mode. Should the operator need to pause the treatment for any reason; the laser must be switched back to "Stand-by" mode. In case of pauses exceeding 1 minute, please press the "Ready" key.
The device must be turned off when left without supervision, to prevent usage by unauthorized individuals.

A T T E N T I O N !
Installing and/or operating the FOX Laser in any other way differing from the one described herein may cause hazardous exposure to radiation.

5.6 NOHD Safety Distance

$$NOHD = \frac{\sqrt{\frac{4P}{MPE * \pi}} - Diameter\ Beam\ Bundle}{Beam\ Divergence}$$

For all FOX models:

Diameter beam bundle:	240µm
Beam divergence in rad:	0,227

Power P:	**9,6W**
Wavelength λ:	**810nm**
Maximum Permissible Exposure MPE:	42,26W/m²
NOHD:	2,37m

Power P:	**4,8W**
Wavelength λ:	**940nm**
Maximum Permissible Exposure MPE:	76,88W/m²
NOHD:	1,24m

Power P:	**14,4W**
Wavelength λ:	**980nm**
Maximum Permissible Exposure MPE:	92,42W/m²
NOHD:	1,96m

Power P:	**12W**
Wavelength λ:	**1064nm**
Maximum Permissible Exposure MPE:	31,82W/m²
NOHD:	3,05m

However, this hazard distance is irrelevant as the access to the laser radiation is blocked by the marked operation room for the laser device.

(See also "Room Requirements" Section 4.2 and "Eyewear Protection" Section 5.2 herein).

5.7 CE Regulations

The FOX Laser system was accredited by LGA InterCert Nuremberg in accordance with the European directive 93/42 for medical equipment. Therefore the device is labeled with the CE mark CE 1275.

The device was tested for electrical compliance as well as for mechanical safety. All parts used by A.R.C. Laser for the FOX Laser comply with CE regulations.

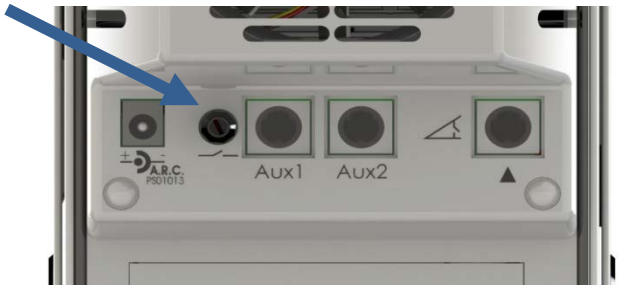
Any additional equipment that needs to be attached to the device must require the official approval of the local inspection authority. No modifications for the device are allowed as these may have a serious risk potential and will void the regulatory approval as well as the warranty.

5.8 External Interlock Plug

At the rear of the console, a removable plug is inserted through a circular socket (see photo below). The plug when fully inserted, enables main power to the console internal circuitry. Should this plug pulled out, the console will instantly shut down.

The plug is intended to be used as an additional safety switch by connecting it to the door of the treatment room. Should the door be unexpectedly opened, laser radiation will immediately drop to zero.

Please be advised that the laser can only operate when the plug is fully inserted into the socket.



5.9 Console Protecting Housing

The FOX Laser has a protection housing optically sealed to prevent laser radiation leakages, and is electrically isolated. Housing should never be opened or modified. Non-authorized personnel should never attempt to carry out any type of service to the console. Console parts should only be removed and replaced by trained A.R.C. Laser GmbH service technicians.

5.10 Safety Switch

The FOX Laser has an internal safety shutter. This safety switch enables the release of laser beam and will open when pressing the "READY key" followed by the pedal switch.

After starting the laser the FOX begins with internal tests. After he has passed all its internal tests and calibrations, the safety switch can give way for the laser radiation.

The aiming beam becomes active only when the laser is switched to a READY mode, the aiming beam is a low power green laser, similar to laser pointers.

5.11 Manual Reset

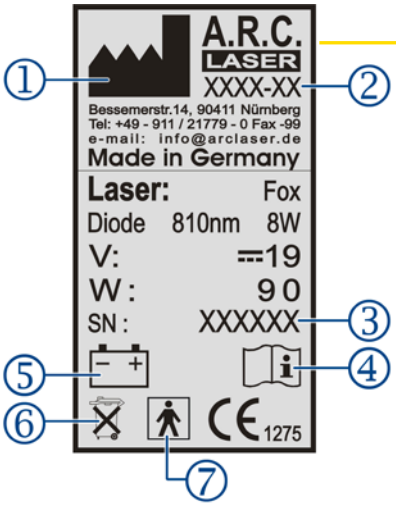
When an error occurs (e.g. power instable etc.), the device changes into the STAND-BY mode. Simply close the FOX Laser cover stand and re-open to make sure the device can reactivate itself. If the device cannot be started again, there is an error which can only be resolved by a qualified personnel. Please contact your local A.R.C. Laser GmbH authorized dealer.

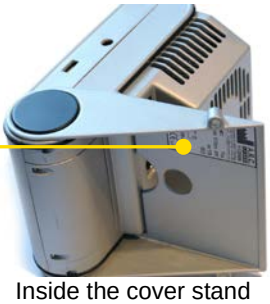
5.12 Stickers Labels and Markings

The FOX Laser has various warning labels in accordance with the European directives and Health Canada, intended to prevent any laser users to become exposed to laser radiation as a result of improper use. You can identify the arrangement of these labels with the following drawings:

IDENTIFICATION PLATE FOX
According to model: 810, 980, 1064 nm (located on the inner side of the cover stand)

① Manufacturer
② Date of manufacture
③ Serial Nr.
④ See Manual
⑤ Battery powered
⑥ No disposal in domestic waste
⑦ Applied Part: Type BF



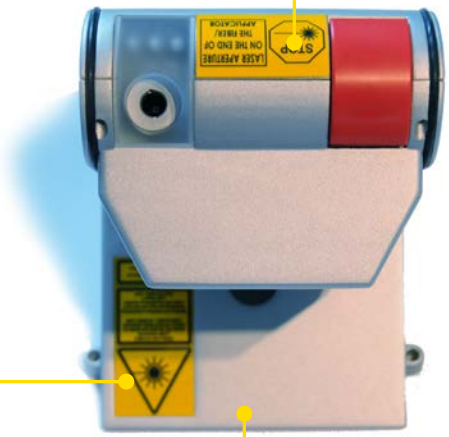

Inside the cover stand

WARNING LABELS

Warning label fiber exit
(Console top)

Warning label
laser radiation
(Cover stand top)

VISIBLE AND INVISIBLE
LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION
LASER CLASS 4 EN 60825-1:2007
RAYONNEMENT LASER VISIBLE ET
INVISIBLE- EXPOSITION DANGEREUSE
DE L'ŒIL OU DE LA PEAU AU
RAYONNEMENT DIRECT OU DIFFUS
APPAREIL À LASER DE CLASSE 4
EN 60825-1:2007
P = 15W λ = 810-1064 nm
P = < 5mW λ = 532 nm



DANGER
VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION
DIODE LASER 810- 1064nm. CW. 10Wmax.
DIODE LASER 532nm. CW. 5mWmax.
CLASS IV LASER PRODUCT

Warning label
laser radiation
(Cover stand top)

5.13 Operating Conditions:

- The FOX Laser is not suitable for use with combustible gas mixtures.
- The FOX Laser has not been tested for operation in heights exceeding 2,000 m above sea level.
- To ensure steady operation in continuous laser mode, device internal cooling must be allowed to operate without any obstruction and in following ambient conditions:
    - Ambient temperature: 10°C to 40°C
    - Air humidity: < 75%

Examples of some applications:

- Nasal mucosa hyperplasia (ENT)
- Parodontose treatment (dental application)
- Vessel coagulation (Dermatology)
- Ciliary body destruction (Ophthalmology)
- etc.

5.14 Electromagnetic Compatibility

The FOX Laser complies with the EMC requirements according to DIN EN 60601-1-2:2007-12. Guidelines and manufacturer's declaration are described in Section 12.

6 User Information and System Introduction

6.1 Dispatching and Unpacking the Device

I case unpacking and installing the device is done under the responsibility of the user:

Enclosed documents, included in the shipment with the FOX laser system, need to be filled out and sent back to A.R.C. Laser GmbH. Outside Germany, these documents will be filled out by your local A.R.C. Laser dealer.

In the event where the device is transported to the user via a courier delivery services, the consignee should take special care that the parcel was delivered in a proper and undamaged condition.

Any visible damage to the outer packaging shall immediately be reported to the transporter and your local A.R.C. Laser authorized dealer. In this case, warranty claims shall only be addressed to the transporter.

Before initial start-up, please read the user manual carefully to fill out the accompanying documents correctly.

6.2 Technical Introduction Training

Upon installation, a staff member from A.R.C. Laser or the local authorized dealer will provide introductory training for the Laser system.

The introductory training will cover the device technical abilities as well as overall safety associated with the installation and use of lasers in general and the FOX Laser in particular.

All individuals working at the vicinity of the laser should attend this introductory training.

One individual with the training and experience to knowledgeably administer a laser safety programe, will be chosen as the person responsible for monitoring and overseeing the control of laser safety.

6.3 Laser Safety Training

The FOX diode laser is designed for medical applications. It may only be used by a physician who received training by an authorized personal. In addition to the trainings offered by A.R.C. Laser, A.R.C. Laser GmbH recommends to attend seminars offered by us. These seminars contain topics like “working with different laser systems” such as the diode laser. Moreover, introductions into the laser safety and the use of lasers in general will be covered in these seminars. We recommend you to make sure that only the person holding the password will use the laser. The password should not be handed to other physicians unless they went through the recommended training for the device.

The fact that even personnel not working directly with the laser should attend the "laser safety” or "laser application” courses, has proven to be very useful. Laser safety, the basic principles of the laser and of laser treatment is mainly discussed in these courses. It is particularly important that the operating personnel attend the laser safety courses. In these courses, extensive training is given to master precautionary measures when working with lasers (e.g. caution in case of combustible material, the importance of laser protective goggles etc.) are dealt with in detail.

Training for the accompanying personnel is offered in addition to the introductory, and is given by the local A.R.C. authorized dealer service person when installing the device.

In this training, special attention is given for safety in general like the laser protective goggles. It also covers clinical information as well as references to the indication but does not intend to be complete and to be used as is, since each patient may require different parameters.

A.R.C. Laser GmbH holds a list of recommended courses as well as laser safety courses available, and can be retrieved from us through our local dealer at any time.

6.4 Medical Introduction Training

The scope of the device medical introduction training is to provide basic information on selected medical applications for the users specific intended use.

Where required, it is possible to attend a comprehensive training course held by an experienced physician. Upon request, please contact your local A.R.C. Laser authorized dealer, or contact us directly.

A T T E N T I O N !
Do not attempt to perform any type of service or maintenance work to the device. Any calibrations or adjustments that require opening the protective housing, should only be carried out by a service technician trained by A.R.C. Laser GmbH. This includes also any type of optics cleaning within the laser system as well as battery pack replacement.

6.5 List of Medical Devices

The FOX Laser packaging includes an enclosed document that contains a list of medical accessories which should be stored in the carrying case or in the event of larger number of accessories, in a similar protected manner. In case of any damage or suspected malfunction in any of the accessories, please contact your local A.R.C. Laser authorized dealer for technical support.

6.6 Medical Device Parts and Accessories

A T T E N T I O N !
Only the parts and applications as specified by A.R.C. Laser GmbH can be used with the FOX Laser. Any use of other non approved accessories may pose a serious risk hazard to the operator and/or patient; As well as not provide the expected result.

Available applicators like: fibers, endo-probes, hand pieces and similar parts are described in detail in the corresponding application manuals.

The basic FOX Laser system includes the following parts (which can be ordered separately at any time):

Part-Name	Description	Item-No.
Foot Switch	Foot switch with hinge and cable	BG03808
Power Supply	FOX Battery Charger	PS01013
Device holder	Easy mount to keep the FOX secure	BG03805
Port Protection	Dust cover plug for the fiber port	ME03855
Carrying Case	Protective metal case for storage and transportation of the FOX Laser and its accessories	VP03101-3
Protective Goggles*	Protective eyewear against laser light	AS01009

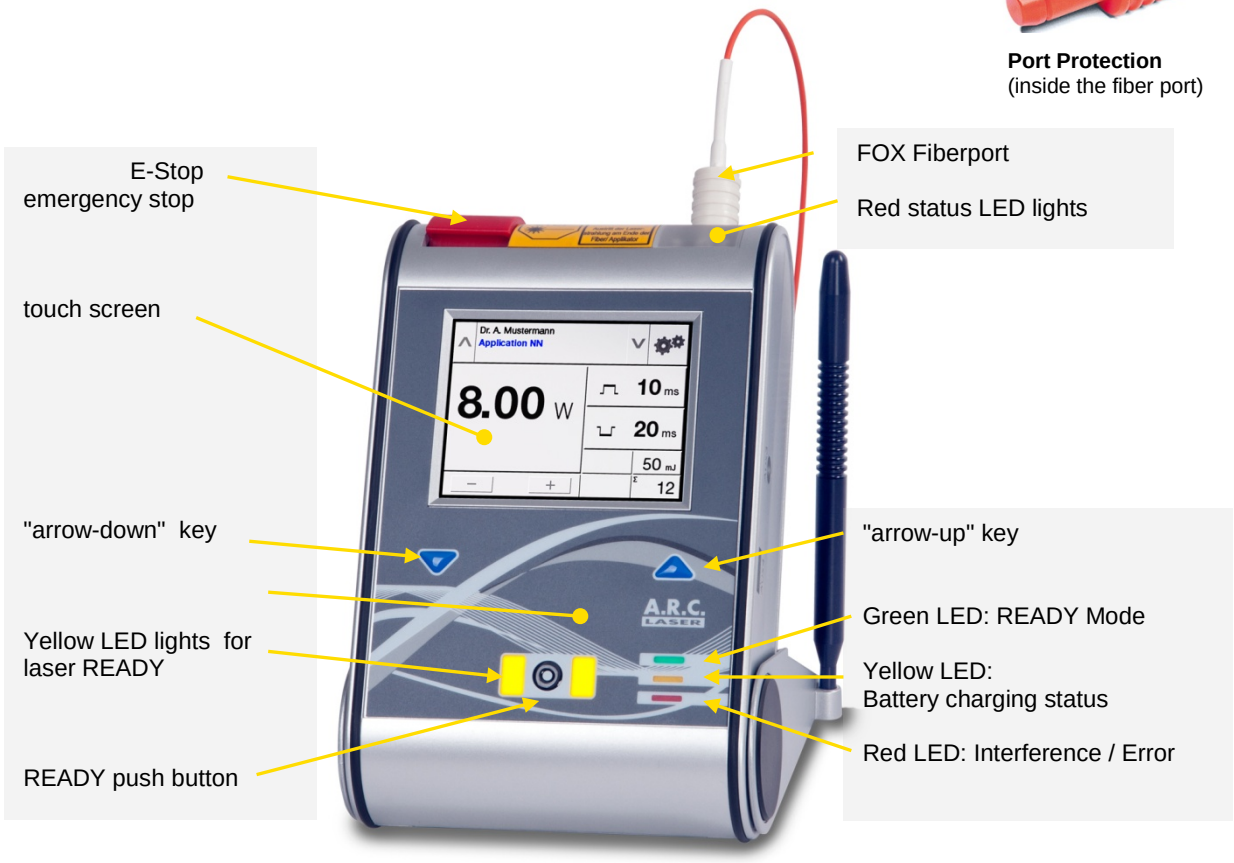
* Protective Goggles are wavelength dependent. There are several models available including types that fit over glasses. Please provide your FOX Laser model when ordering.

For further information about accessories please contact your local distributor.

6.6.1 **Housing Front**

The front panel of the device consists of the following controls and keys:

Port Protection
(inside the fiber port)



FOX Fiber port

The FOX Laser has a fiber port at the head of the device, see Section 7.4, intended to incorporate the patented A.R.C. Laser click plug for a wide range of hand pieces and applicators. To protect the fiber port A.R.C. inserted the protective cap.

There are two versions of the fiber port: the silver 300 micron port and the yellow 400 micron fiber port.

300 micron

400 micron

Fibers and hand pieces (single use) to be used in systems with the 300 micron port do have a white or red connector, in case of the 400 micron port they do have a yellow connector.

A T T E N T I O N !
Fibers and hand pieces which are designed to be reused do have a green plug. They cannot be assigned to the appropriate system in accordance with the color of the plug! In this case the user has to be carefully look at the label of the packaging of the fiber or hand piece!

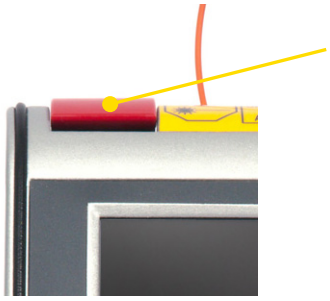
A T T E N T I O N !
Never work with a tool at the fiber or at the fiber port.
Fibers may break – do not bend! Protect fiber ends against dust and dirt. Never use defective fibers.

6.6.1.1 READY Key

The READY Key is a black circular push button with two lateral yellow LED guides

Press the *READY Key* button once and release, to switch to READY mode. The two yellow LED guides will start flashing, accompanied by a beeping sound. After approx. 3sec the two lateral yellow LED guides will remain on, indicating that the device is now ready for operation. Pressing the *READY Key* button again, will deactivate the READY mode. A confirmation beeping sound will be heard and the two lateral yellow LED guides will turn off.

6.6.1.2 Laser STOP, E-STOP



The E-STOP button is on the top left side of the device. If the E-STOP button is pressed while starting the device, the screen will remain black, no LED will highlight and the device will not be able to start as its power supply voltage is cut off.

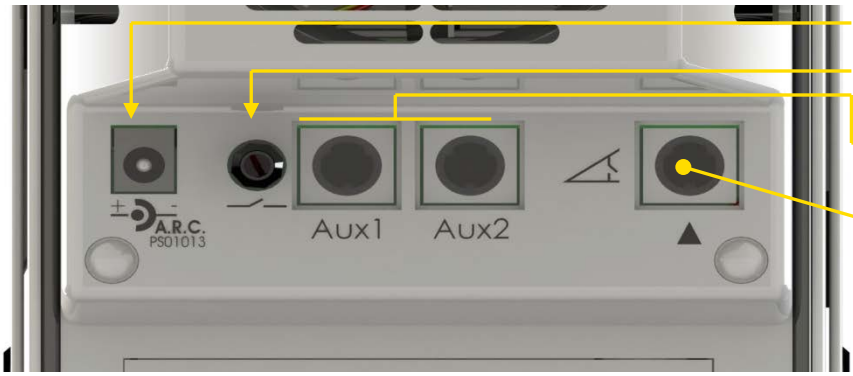
Solution: Pull up E-STOP, and the device can be started (see 7.2)

Pressing the E-STOP button while working with the FOX Laser, will instantly cut off the laser output.

Solution: Pull up E-STOP, and restart the device. (see 7.2)

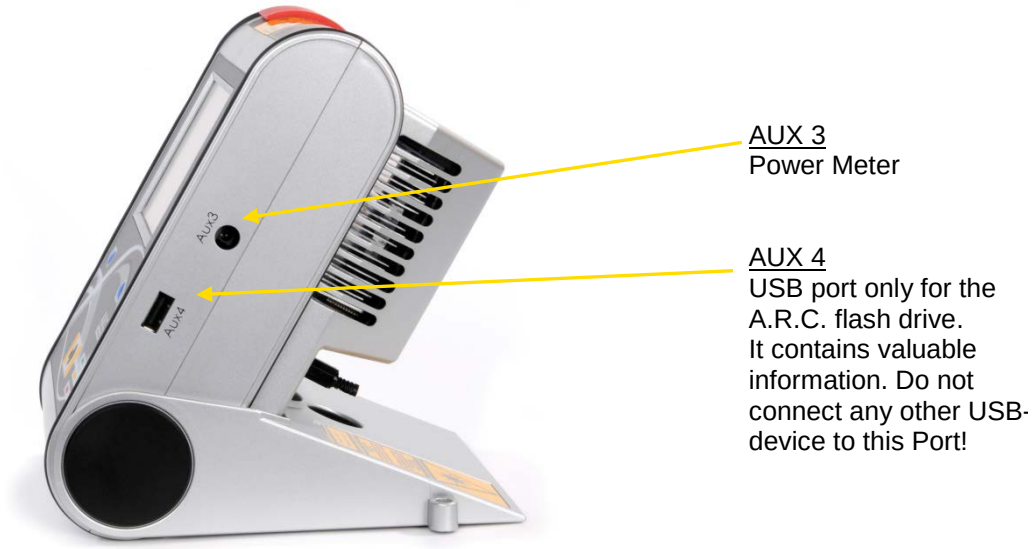
6.6.2 **Rear Panel**

The following connector sockets are located at the rear panel:



6.6.3 **Right Side Panel**

The following connector sockets are located at the right side panel:


AUX 3
Power Meter
AUX 4
USB port only for the A.R.C. flash drive. It contains valuable information. Do not connect any other USB-device to this Port!
Aux3
Aux4

6.6.4 **Sockets**

It is prohibited to use the device's sockets for other usages than those detailed here.

Socket	Description	Note
Power	Charging device PS01013	To charge internal batteries
Door-Interlock	Connecting the door-interlock switch	
AUX 1	External eye protection filter	U_{max} = 3,3 V; I_{max} = 330mA
AUX 2	Isolated port – works as a remote control to activate warning light	Max. 24V; do not plug in a device
AUX 3	Connector for the A.R.C. powerMeter	
Foot switch	Connector for the A.R.C. foot switch	
AUX 4 - USB	USB connection for A.R.C. flash drive	Contains helpful information Do not connect any other USB-device

7 Operation

A T T E N T I O N !
The FOX Laser may only be operated by personnel that undergone relevant training for the device and that proves the necessary knowledge for the laser's applications

This part of the manual describes mainly the technical aspect of the device functionality without providing extensive details on its medical use. A more elaborated medical use is detailed at A.R.C. Laser application manuals, which can be obtained through your local authorized distributer.

Device settings as well as various parameters adjustments should only be carried out in compliance with the operating instructions manuals. Any modifications or settings not indicated in the operation manuals may cause malfunctions.

7.1 Preparation

The FOX contains an internal rechargeable battery. A power supply unit is included with the basic system, which needs to be connected to the charger port at the rear panel. The power supply unit will shut the charging current when the battery is fully charged. Charger input voltage ranges between 100V and 240V. Due to security reason your FOX can only be operated with the power supply distributed by A.R.C. Laser.

Please follow the following steps when preparing the device to operation, in order to avoid unnecessary troubleshooting or even possible malfunctions.

- Is the battery charged or is the mains cable at the rear panel connected?
- Please connect the mains when the device is switched off.
- Has the strapping port for the external interlock been plugged in?
  – or, if applicable: has the door interlock contact been connected to the laser?
- The fiber port should be empty.
- Has the A.R.C. Laser USB stick been unplugged from the USB port?
- Are the fibers and hand pieces that are to be used, free of any damage?
- Is there sufficient number of protective goggles ready to be used?
- Has the pedal switch been plugged in?

A T T E N T I O N !
A warning lamp/s outside the treatment room door/s must be switched on as soon as the laser starts to operate; the doors have to be marked as laser rooms, visible from outside (with the warning signs).

A T T E N T I O N !
Since the green aiming beam shares with the infrared laser beam, the same optical delivery system, it provides a very good indication for checking the intactness of the laser optical delivery system.
If the target spot does not appear at the distal end of the laser delivery system, or if it has low intensity, or appears to be diffused, this may indicate a damaged or not properly installed delivery system of the unit.

7.1.1 Installation Site

We recommend placing the FOX Laser on a solid, even surface. A suction cup mount is included in the carrying case to secure the device.

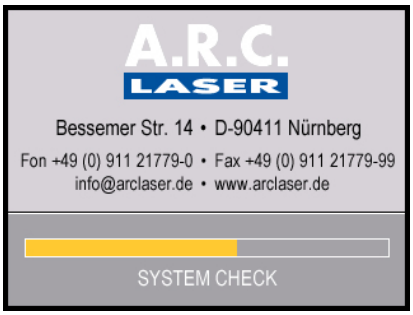
7.1.2 Suction Cup Mount

Moisturize the cups and press them firmly onto the even surface. Verify if they position firmly by slightly shaking or pushing the suction cups.

suction cup mount

7.2 Starting the Device

Switch on the device by pressing the two arrow keys simultaneously for at least two seconds. The red status LEDs at the fiber port will light continuously and the green starting LED will begin to flash. After about 30 seconds, the startup screen will appear.


A.R.C.
LASER
Bessemer Str. 14 • D-90411 Nürnberg
Fon +49 (0) 911 21779-0 • Fax +49 (0) 911 21779-99
info@arclaser.de • www.arclaser.de
SYSTEM CHECK

The FOX Laser executes its system check automatically upon startup.

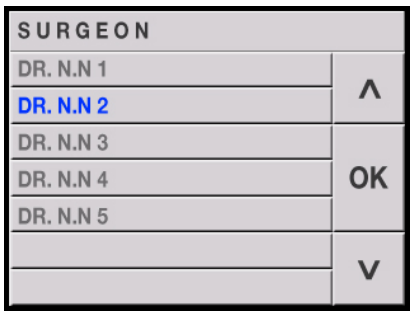
Once the system check has been completed, you have to enter the password ("**0000**"). See chapter 7.3.4.4 to modify the password.

7.2.1 Fiber Port / Fiber Coupler

The fiber coupler has a control mechanism which can prevent the device from switching into the READY mode as long as no fiber has been connected.

Please do not insert any objects or liquids into this port as this might damage the ceramic disk, used for centering the fiber.

7.2.2 Select a Surgeon / Add a new surgeon



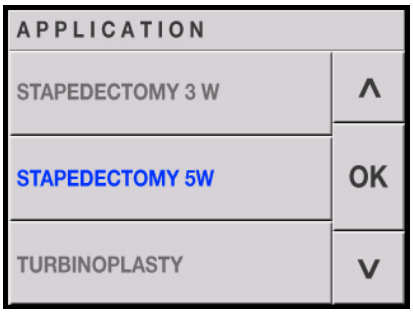
Choose your name

Select the desired name by touching the specific line at the touch screen. With OK you proceed to select a program.

Change a name with pressing a line for more than 2 seconds.

Insert your name via keypad and press OK to leave the screen.

7.2.3 Select a Program



Select your application. In this case program no. 2 has been selected.

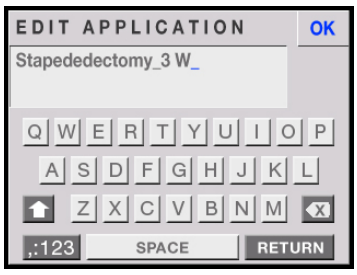
Select the desired application with a finger tip

With the arrow keys, you will get to other applications /programs.

The application selected is highlighted in blue and will be confirmed when you press the OK field. The names of the programs were preset; you can change them at any time.

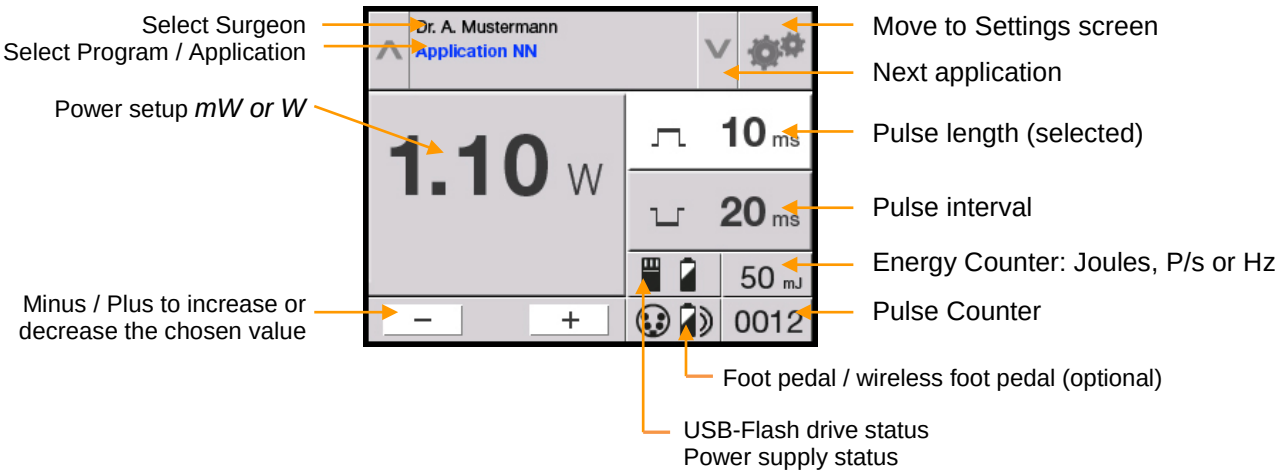
Change the names of the programs by keeping the relevant field pressed down (2 sec.)

The input screen will appear. Enter the desired name and confirm with the OK key. With the “123” key, you leave the alphabet screen.



7.3 Working with Selected Programs

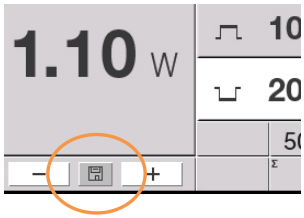
7.3.1 Display / Main Menu



7.3.1.1 Saving parameters

Section 7.2.3 describes how to modify program names. In addition, you can also change the parameters for power / pulse length / pulse interval as described in the following 3 sections.

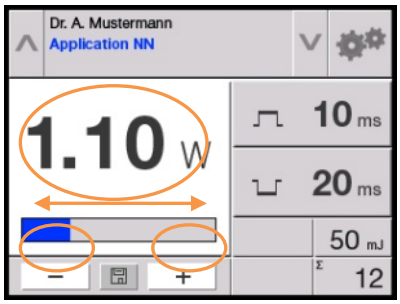
To store the modified parameters, please press the save button. This button appears only after you change a value.



7.3.1.2 Power

After pressing the power display (Watt), you can adjust its value with its plus or minus-button. By keeping the field pressed down for a little while, a power bar will appear, in which you can directly scroll to the required power value.

The displayed value may vary from the emitted value at the distal tip, by a range of ±20%.

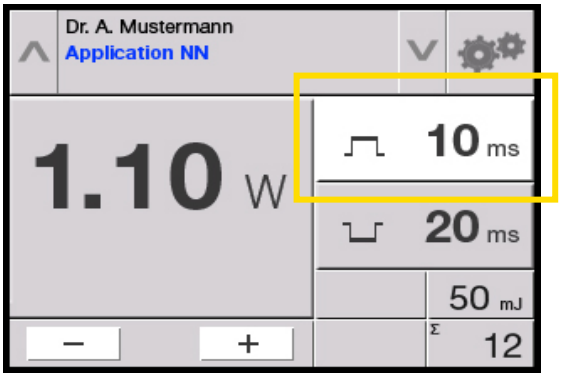


7.3.1.3 Status USB Flash Drive

If inserted the Flash drive icon will show up. In case the drive is defective or not inserted the display does not show this icon.

7.3.1.4 Pulse Length Adjustment

You can adjust the pulse length through the pulse length menu.



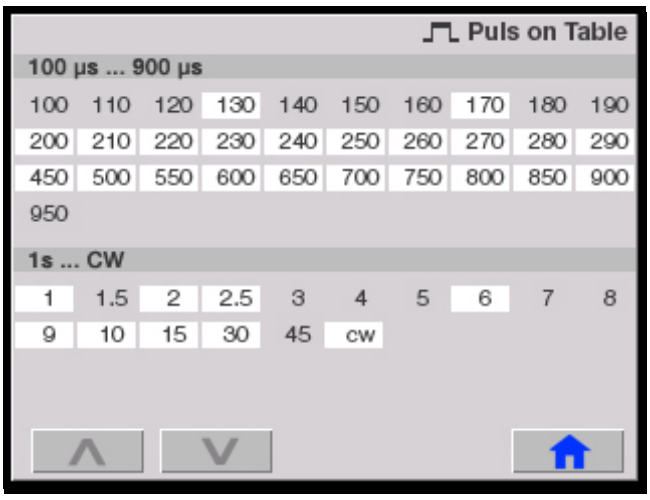
µs	ms							SEC	
100	1	12	26	48	100	210	600	1	7
200	2	13	28	50	110	220	650	1,5	8
300	3	14	30	55	120	230	700	2	9
400	4	15	32	60	130	240	750	2,5	10
500	5	16	34	65	140	260	800	3	15
600	6	17	36	70	150	280	850	4	30
700	7	18	38	75	160	300	900	5	45
800	8	19	40	80	170	350	950	6	CW
900	9	20	42	85	180	400			
	10	22	44	90	190	450			
	11	24	46	95	200	500			
CW = continuous wave									

Choose your favorite values from this table.

below: Screen with highlighted „Pulse on“ values

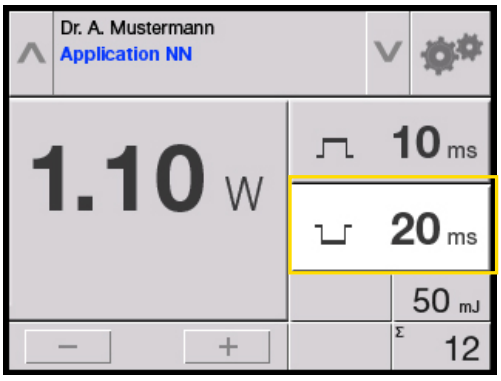
Therefore hold the button for at least 2 sec. Highlighted values are preset. Add or deselect values of your interest to modify your presets as necessary.

The „new“ Preset-table is activated by leaving this screen via this „HOME“ button.



7.3.1.5 Pulse Interval Adjustment

While keeping the pulse interval field pressed down, you will reach the interval release table where you can select (marked) and preset individual parameters.



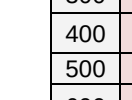
µs	ms							SEC	
100	1	12	26	48	100	210	550	1	8
200	2	13	28	50	110	220	600	2	9
300	3	14	30	55	120	230	650	3	10
400	4	15	32	60	130	240	700	4	15
500	5	16	34	65	140	260	750	5	30
600	6	17	36	70	150	280	800	6	45
700	7	18	38	75	160	300	850	7	SP
800	8	19	40	80	170	350	900		
900	9	20	42	85	180	400	950		
	10	22	44	90	190	450			
	11	24	46	95	200	500			
SP = single pulse									

Choose your favorite values from this table.

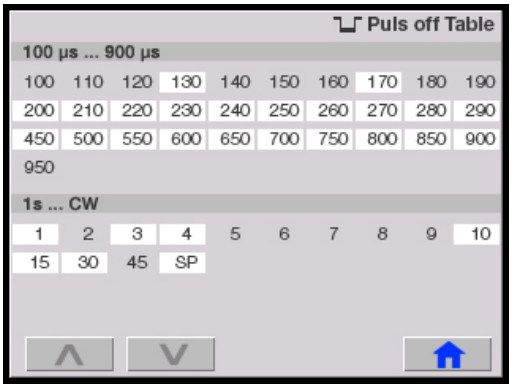
below: Screen with highlighted „Pulse on“ values

Therefore hold the Pulse-off button for at least 2 sec. Highlighted values are preset. Add or deselect values of your interest to modify your presets as necessary.

The „new“ Preset-table is activated by leaving this screen via this „HOME“ button.



Thus, the highlighted fields constitute an individual preselecting, and only these parameters will be available.

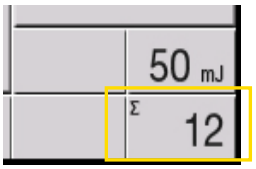


Example: If the pulse length is 10 ms and the pulse interval is also 10 ms, 50 pulses per second will be applied when the pedal switch is pressed down.
Intervals between the individual laser pulses are important to make sure the tissue treated has sufficient time to cool down.

7.3.1.6 Pulse Counter

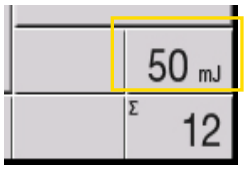
The triggered pulses are accumulated. The device automatically counts the laser pulses triggered by means of the foot pedal or set by pulse repetition rate. The maximum number of pulses registered is 9999.

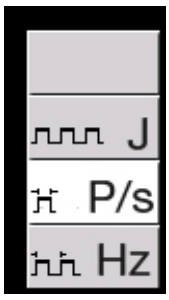
To reset the field “0000” you need to tip on it.



7.3.1.7 Energy Counter (J or P/s or Hz)

Three versions are available in this tally field:





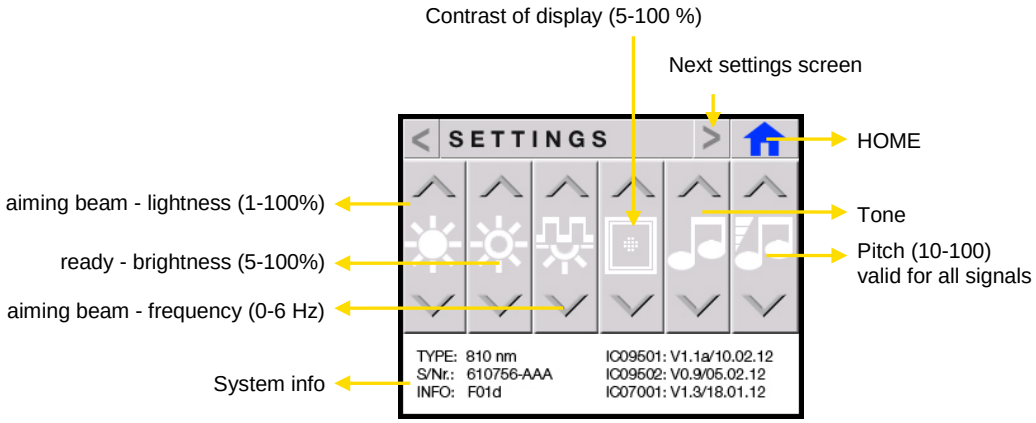
Energy joule: The displayed energy value is the product resulting from the set power and the actual time of exposure as well as the number of pulses triggered. The unit automatically changes from mill joules (mJ) through Joules (J) to kilojoules (kJ), according to the energy added.

Power/second: P/s stands for the result of the power set and the actual time of exposure depending on the pulse length and the pulse interval. The display of the unit also changes automatically from mW to W according to the setting.

Frequency Hz: The displayed frequency value is calculated from the pulse length and the pulse interval per second, displayed in Hz.

7.3.2 Settings - Submenu 1

Leave the main menu to enter the submenu by pressing the MENU key.

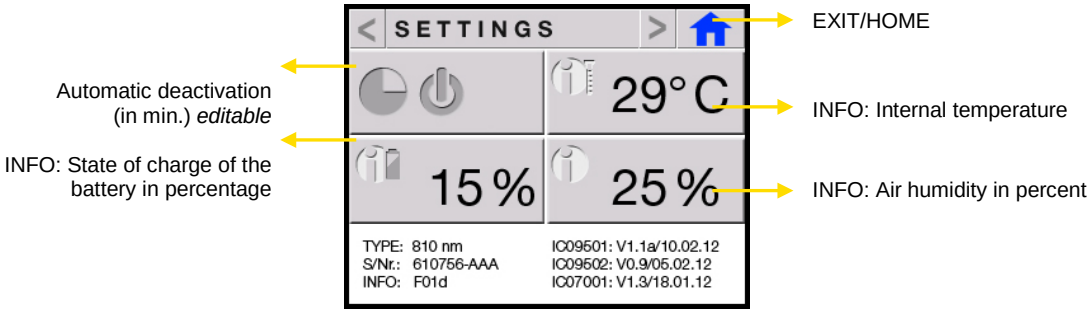


The individual parameters can be adjusted with the up/down buttons.

Reduce Power Consumption: If you do not work with the maximum brightness of the aiming beam, we recommend you to reduce the parameter settings and to vary the aiming beam frequency, as maximum power is consumed with maximum setting.
The brighter the display, the higher the power consumption.

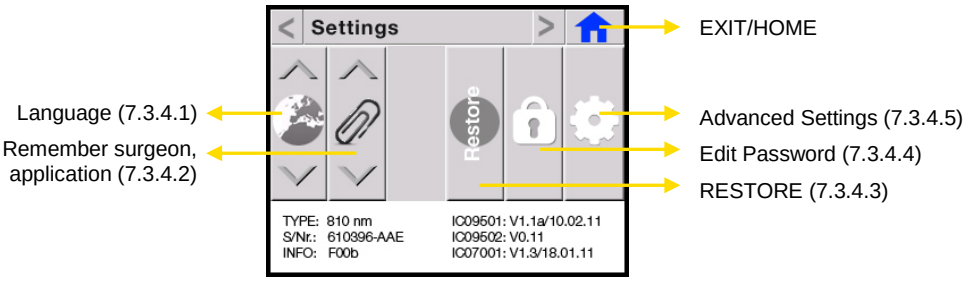
7.3.3 Settings - Submenu 2

Leave submenu 1 with the arrow key „right“ and get into the next submenu. Here you can only modify the automatic deactivation.



7.3.4 Settings - Submenu 3

Leave submenu 2 with the arrow key „right“ and get into the next submenu 3. Here you can change the language of your FOX and alter the memory function.



7.3.4.1 Language

Pick your desired language with the arrow buttons

7.3.4.2 Remember surgeon and application

Once you choose the remember icon (indicated dark), you set the Memory-function and the FOX will remember the last settings for surgeon and application. At the next Starting-Routine the screen for Surgeon and Application will be skipped. The Memory is switched off when the clip-icon is bright.

dark

bright

7.3.4.3 RESTORE

This function restores default settings and deletes all kind of user settings and modified parameters. Programs and Settings are restored.

7.3.4.4 Edit Password

This screen is to modify your user-password (Standard is “**0000**”) - you need it at the end of the starting process. A password consists of 4 numbers. By pressing the numeric

keypad you fill the input box. After 4 numbers there is an automatic *Return*.

The Routine will guide you through the menu:
① Old Password: Enter the present password
② New Password: Enter your new password.
③ Confirm Password: Re-Enter your new password.

7.3.4.5 Advanced Settings

Only trained personnel should use the features of the advanced setting screen.

7.4 Charging the battery

Insert the Power Supply Art. Nr.: PS01013 into its socket at the rear side of the FOX.

Switch on the device (see 7.2) and enter your password.

Charging Process is initiated. The orange LED shows up.

If you might want to switch off your FOX, the charging process will be continued.

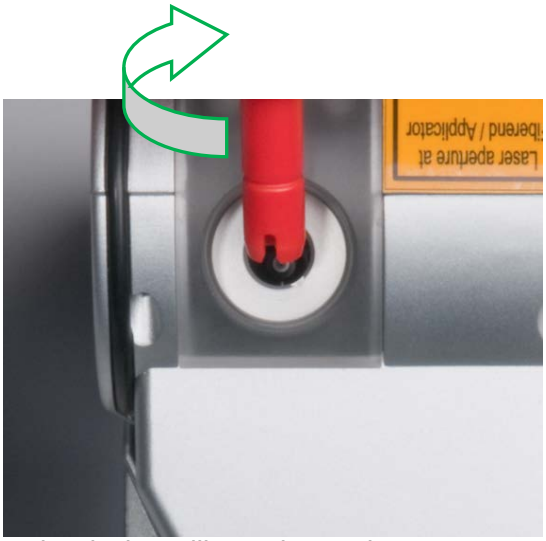
As soon as the battery is completely charged the orange LED will switch off.
The green LED will shine on.

7.5 Inserting the Applicator

When the preselected power and pulses comply with the treatment parameters, the applicator can be plugged into the laser aperture.

Gently push the applicator plug into the socket until it firmly "clicks" into place. In case it does not click in correctly, try to twist the plug inside the socket.

Plugging in the applicator



If the plug has not properly clicked into place, the device will not change into READY mode, and the FOX Laser will not work.

Please pay attention to a clearly perceptible "click" when inserting the plug! You may need to twist the plug a bit while its partially inserted in order to be able to fully click it into place.

Once the plug has been locked in place, you can hold the applicator/ hand piece in your hand. At this point, infrared radiation can be emitted through the applicator upon activation of the foot pedal. Therefore, please ensure the applicator is aimed away from any person, other than the patient target area, and is not pointed toward flammable materials.

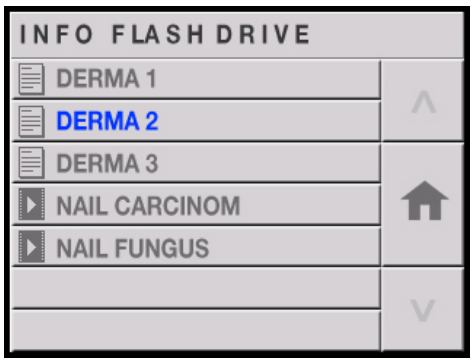
7.6 Ready Key

The READY Key is a black circular push button, with two lateral yellow LED guides.

Press the READY Key button once, to switch to READY mode. Upon pressing the two yellow LED guides will start flashing, accompanied by a noticeable beeping sound. After approx. 3sec the two lateral yellow LED guides will remain constantly on, indicating that the device is now ready for operation.

Pressing the READY Key button once again, will deactivate the READY mode. After pressing a single confirmation beep sound will be heard and the two lateral yellow LED guides will turn off and the aiming beam will go out.

7.7 USB flash drive



You can connect the USB flash drive included with the system to the USB port located on the right side of the console. To access the content of the flash drive, you need to touch the question mark on the A.R.C. infoscreen. (see Section 7.3.4) In the provided flash drive you can find useful information, including videos for a wide range of applications.

Enjoy paging through!

7.8 Switching Off

Switch off the FOX by folding back the cover stand. If you do not plan to use the FOX Laser for a long time, stow the laser in its carrying case.

7.9 Power Save

After 5 minutes of inactivity the FOX automatically goes to Stand-By to save power.

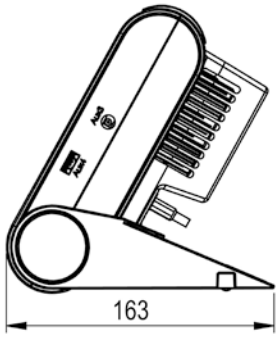
- The TFT screen gets dark
- The green status LED indicates with 1 Hz

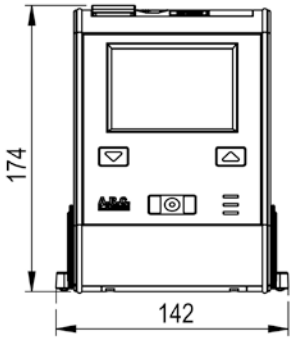
To “wake” the laser just tip the touch screen or one of the blue arrow keys.

After 5 more minutes of inactivity the laser switches off completely. You will need to restart it by pressing both blue arrow keys.

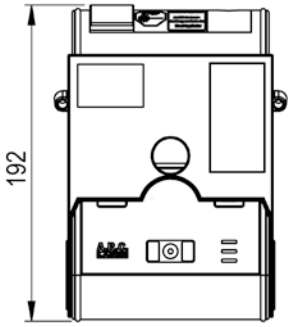
8 Technical Data

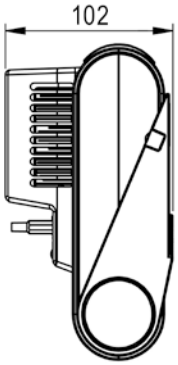
8.1 Dimensions





device open





device closed

8.2 General

Model FOX	diode laser
Cooling	internal, forced air convection
Weight	1.2 kg
Dimensions	H 17.4 cm / W 14.2 cm / T 16.3 cm with opened foot

8.3 Laser Data

Wavelength	**Power**
810 nm	8 Watts max.
940 nm	5 Watts max.
980 nm	12 Watts max.
1064 nm	10 Watts max.

Display	Digital touch screen display
Pulse lengths	100 µs to 30 sec, CW
Shot frequency	Single pulse (SP), 0.02 Hz to 5,000 Hz
Power transfer	Fiber 200µm, 300µm, 400µm, 600µm with or without hand piece
Aiming beam	532 nm green < 1mW
Operation mode	Continuous wave (CW) or pulsed in variable brightness

8.4 Power Requirements

External power requirement	100 - 240 V AC, 47/63 Hz, 1.06-0.45 A
Charger output / Console input	19 V DC, 4.74 A
Battery	10.8 V , 26.4 Wh, Li-Ion (by A.R.C. Laser)

8.5 Classifications

Laser class 4
(Classification according to EN 60825-1: 2007)

Aiming beam laser class 2
(Classification according to EN 60825-1: 2007)

Electrical protection class II
(Classification according to IEC 60601-1)

9 Service

9.1 Introduction

The device was designed, developed and tested according to research based on state-of-the-art technology. As a rule, similar devices have a service life exceeding 5 years. This product service life is defined to be 10 years in order to guarantee the availability of its spare parts during this period of time. However, to make sure the product is in good working order, the device can display its internals working status through the touch screen display.

In the rare situations when the device does not work, you can use the “Troubleshooting” section included in this manual, to isolate the problem. The solutions given therein will most likely allow you to solve the problem yourself. However if the problem cannot be solved, please contact your local A.R.C. Laser authorized dealer for technical support.

A T T E N T I O N !
Do not attempt to perform any type of service or maintenance work to the device. Any calibrations or adjustments that require to open the protective housing, should only be carried out by a service technician trained by A.R.C. Laser GmbH. This includes also any type of optics cleaning within the laser system as well as battery pack replacement.

9.2 Safety Check

A T T E N T I O N !
The device needs to undergo a safety inspection every 24 months carried out by qualified personnel.

In the event where the device is out of order and/or not safe to operate, remedial maintenance is required and/or the operator shall be informed of the hazard originating from this device.

The device must not be operated any longer as soon as it reveals any faults which may pose hazard to the patients, to the operating personnel or third persons. In this case, the operator shall immediately inform the responsible regulatory authority thereof.

A T T E N T I O N !
Please note that the laser device may only be operated by people who can guarantee proper handling due to their training and knowledge as well as due to their practical experience. Responsible people have to be instructed at the place of operation when the device is installed.

9.3 Care and Maintenance (by the user)

The following care and maintenance can be done by the user.

Before any type of maintenance, always remove the battery charger plug from the FOX Laser console, and any applicator that may have left still attached.

The housing may be cleaned with a damp cloth. Clear water or a neutral cleaning solution (e.g. mild common cleaning solution for household) may be used. Pay attention to never use a wet cloth, because water must not enter the device in any case!

A disinfection of the surface by wiping the surface is possible: Disinfection solutions like DescoseptAF* or a comparable disinfectant (e.g. Mikrozid AF) can be used (*DescoseptAF: Dr. Schumacher GmbH (www.schumacher-online. de))

DescoseptAF solution contains about 42% Ethanol and about 0,05% Didecyldimethylammoniumchlorid.

Also other disinfectants can be used, as if they are not aggressive or contain acids, which affect the material surfaces of medical devices. Following the guidelines of the manufacturers also agents on the basis of quaternary ammonium compounds, as e.g. TPH protect (company Schülke), or Mikrobac® forte from Bode are suitable. According to the manufacturers, these agents can be used on sensitive surfaces (e.g. acrylic glas), or metal (stainless steel (V2A), aluminium, copper, brass) and plastic (PA, PE, PP, PS, PU, PVC, ABS, silicon, rubber, latex, Makrolon®, Plexiglas®, Teflon®).

In case the FOX is combined with another device, please check the regulations hereof.

Protect the device against water, do not expose to rain or splashes.
Penetrating water may cause a serious malfunction. Do not drop or rinse in any solution or water. Please avoid wet cloths in all cases.

Do not use any chemicals or aggressive agents!
Chemicals or aggressive agents can lead to damage at the surface of the device and damage inside if they penetrate the device.

A T T E N T I O N !
Never look directly into the laser beam emitted from the fiber once the foot switch has been activated, as this will cause a severe eye injury. Always switch off the laser and disconnect it from the power cable when cleaning the console and components.

9.3.1 Accessories Cleaning

9.3.1.1 Pedal Switch

Please refer to 9.3 “Cleaning of the FOX”

9.3.1.2 Protective Goggles

Please follow to the letter, the cleaning instructions provided with the protective goggles that were supplied with the system.

As a general rule, never use abrasive chemicals that may harm the goggles coatings, nor use cloth with fiber that can scratch the goggles surface.

9.3.1.3 Applicators (for non-sterile use)

Please refer to 9.3 “Cleaning of the FOX”

9.4 Error Detection

The FOX was developed and designed as a modular system. In addition, all its components had to undergo rough shake tests as well as temperature testing. In case of an error, you can start by isolating the problem with this manual. In most cases, you should be able to resolve the problem yourself. If the problem persists, please contact your local A.R.C. Laser authorized dealer for technical support.

However, we do hope that the device will work flawlessly for many years.

When an error occurs in the system, the error will be displayed along with a symbol to identify the error (see section 11 - Symbols Description).

Other error causes might be due to:

1. Battery operation: Make sure the battery has been charged.

2. Interlock: The strapping plug should be fully inserted to the device and the door contact switch should be closed.

3. The red DEACTIVATION button on the top of the device needs to be pulled up.

9.5 System Self Check

In general, a system self check will run after turning on the device, and intended to check all important functions. If a failure occurs, you will be informed immediately and the error detail shows up on the screen.

We distinguish between two types of errors:

1. Dynamic errors (interlock errors), i.e. errors that can be easily resolved or resolved after ordering a spare part from A.R.C. Laser GmbH.
   Such errors may include:
   - Laser STOP button was pressed down
   - Interlock plug missing, disconnected or defective
   - Pedal switch pressed down when turning on device, or defective

2. Static errors, errors which require contacting A.R.C. Laser service department. (or the local authorized dealer). For these usually an error message will appear in the display and can assist to identify the problem when calling for service.

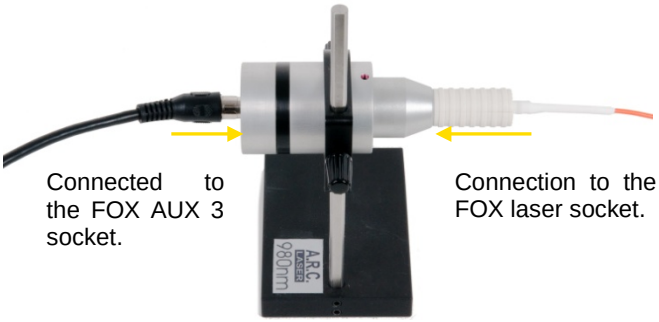
9.6 Troubleshooting

The following errors cannot be identified by the system self check and have to be checked by the user:

Problem	Potential Error	Troubleshooting
Screen is black	Laser is in Sleep mode	As a standard the laser falls asleep after 5 min of inactivity. Touch the display or a blue arrow-key to activate the device.
No aiming beam visible	Laser is in Stand-By mode	Aiming beam becomes visible only when the laser is in READY mode. Switch the laser to READY mode
	Aiming beam brightness set at 0	Increase the parameter for aiming beam brightness
	Fiber is not properly inserted	Twist the fiber connector inside the socket with a light movement inwards
	Aiming beam - diode defective	Contact your A.R.C. Laser dealer
No laser beam but aiming beam visible	Pedal switch non plugged in	Check if pedal switch is correctly plugged in
	Battery of the Wireless Foot Switch is empty	You might have to charge the foot switch batteries
	Wireless Foot Switch is out of reach	Place the foot switch at a place next to the laser
	Pedal switch defective	Contact your A.R.C. Laser dealer
No aiming beam and no laser beam	Fiber optics not connected to laser or hand piece not correctly plugged in	Check the correct fitting of the fiber or hand piece

For a complete list of error codes, please see Section 11.

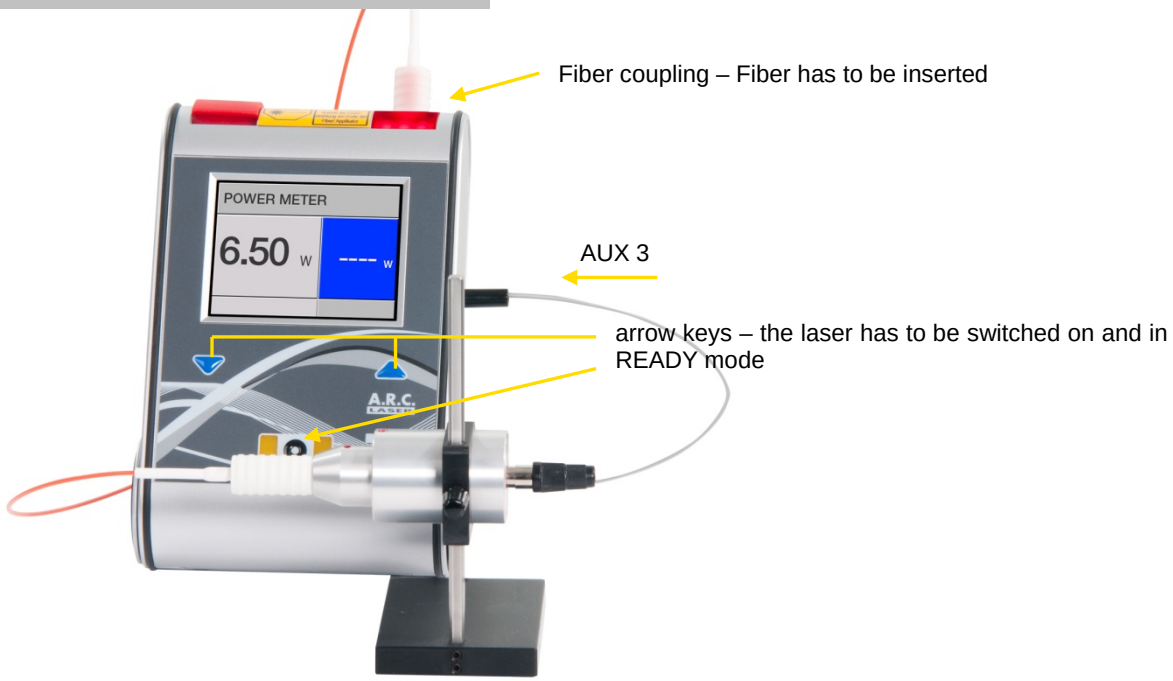
9.7 Power Calibration



To this effect the measuring head has to be connected as shown on the right.

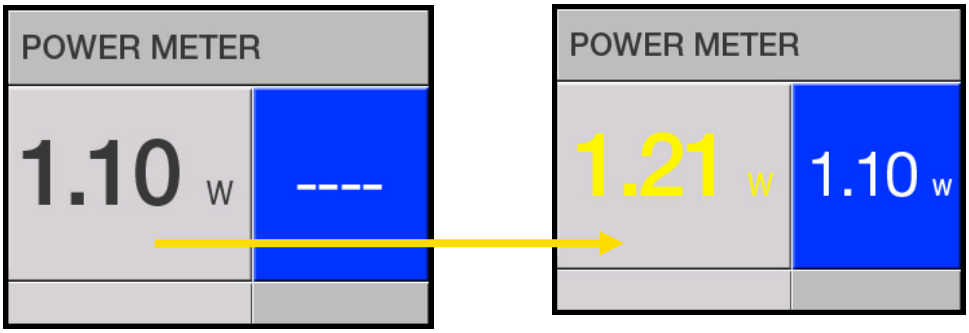
By connecting the laser measuring head with the FOX Laser, the power meter menu will open. The power display will then show the actual parameter, the laser gives you at the fiber end. To this effect, keep the pedal switch pressed down. The display may now be subject to minor fluctuations in decimal places.

Connecting the power meter

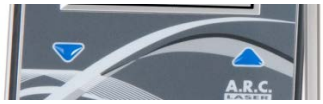

Fiber coupling – Fiber has to be inserted
POWER METER
6.50 W
---- W
AUX 3
arrow keys – the laser has to be switched on and in READY mode

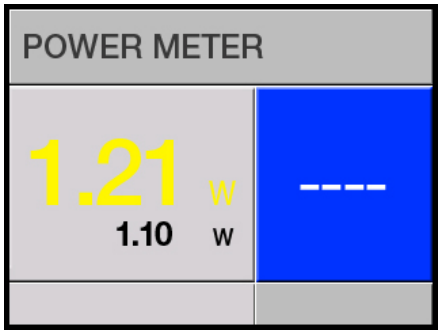
While keeping the pedal switch pressed down — simultaneously press the two blue arrow keys. This is how the FOX Laser calibrates itself thus displaying the real output power measured.

The FOX Laser can be disconnected from the measure head. You can continue your work safe in the knowledge of getting real power parameters displayed. You can recognize the calibrated parameters by the fact that they are shown in yellow.



Press both blue arrow keys to save the new calibrated setting.





The power calibration will be preserved as long as the fiber remains in the device.

Calibration will only be stored, when the deviation between old and new value is less than 20%

As soon as the fiber is plugged out, the calibration is deleted and the pre-settings are imported back again.

A T T E N T I O N !
Should you have several FOX Laser devices with different wavelengths, take care that the wavelength of the measure head corresponds with the wavelength of the laser. Otherwise, the measurements will be faulty and may result in incorrect output power and cause damage.

Nevertheless, it is important to calibrate the power display externally with a power meter at two-year intervals. This may be affected by the service team in the course of the safety check at two-year intervals.

In case of any deviations out of tolerance between measurement and power delivered by the system the customer or even the field service technician should not perform any optical adjustment inside the device. Should the displayed parameters do not correspond with the actual parameters, ***Do not continue using the device any longer and ask for our customer service immediately.***

9.8 Wireless foot pedal (optional)

As an option your FOX will be delivered with a wireless foot pedal.

During the start routine the FOX discovers you will be asked to connect the foot pedal with the laser.

This Symbol tells you to push the pedal .

In the same time, the symbol for the status of the wireless foot switch appears on the display.

Once the wireless foot switch is recognized, the symbol changes to normal condition.

There are 4 versions, which show the current state of charge of the battery.

Battery is fully charged

Battery is sufficiently charged

Battery ought to be charged

Battery must be charged. Otherwise a failure free connection cannot be assured

9.8.1 Charging the battery for the wireless foot switch

Retreat the battery from the battery compartment. Therefore unscrew the cap counterclockwise.

Retreat the battery from the battery compartment. Therefore unscrew the cap counterclockwise. The charging over night normally ensures a fully charged battery.

After charging, the battery can be used as usual.

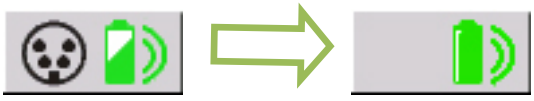
9.8.2 Cable-connected foot switch

As an alternative to the wireless solution, you can always switch to the cable-connected version

By pressing the symbol for the wireless foot switch (here red as an example), it changes after a few seconds to the symbol for the cable-connected version.

9.8.3 Go back to the regular foot switch

By pressing the symbol for the cable-connected foot switch, it changes automatically after a few seconds into the wireless function mode:



9.9 Proper Disposal

When electronics and other potentially hazardous wastes are improperly disposed of, they can harm public health and the environment. Batteries and e-waste contain toxic heavy metals such as lead, mercury, and cadmium.

Many local governments offer assistance to companies that wish to safely dispose of these products. Contact your local government's recycling or solid waste management department to learn more about the services it provides. This laser must not be disposed in your garbage. A.R.C. Laser would be very happy to assist you in the question of how to dispose the device properly.

All the applicators and probes should be disposed according to the valid laws, rules and guidelines of your country. A.R.C. Laser will help you to find out which materials have been used to produce your specific probe/applicator.

A.R.C. LASER GmbH
Bessemerstr. 14
D-90411 Nürnberg
Tel: +49 911 21779-13 (-0)
Fax: +49 911 21779-99
E-Mail: service@arclaser.de

10 Customer Service

10.1 Warranty Information

A.R.C. Laser GmbH provides a two-year warranty. Within these two years, any parts showing a defect will be replaced free of charge. This does not include any optical parts such as hand pieces, fiber optics or built-in elements and purchased parts acquired from a third party. Our warranty covers the repair works and the replacement of defective parts. However, we reserve the right to renew even complete units and to adjust them to the technical progress.

Refer any and all claims or defects to

A.R.C. LASER GmbH Bessemerstr. 14, D-90411 Nuremberg

Phone: +49 911 21779-13 (-0), Fax: +49 911 21779-99, Email: service@arclaser.de

Repair works carried out by third parties or modifications of the device void the warranty claim. The use of parts other than those approved together with the device or purchased from other suppliers also voids the warranty for the complete device. Any parts, units or modifications of the device require the explicit written consent of A.R.C. Laser GmbH.

10.2 Warranty Consignments, Packaging

A warranty claim for defective parts, malfunction or damage of the housing of the device shall be passed on to A.R.C. Laser GmbH within 24 hours. Parts returned during the warranty period (upon the explicit request of A.R.C. Laser GmbH), are subject to the written confirmation by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device will be provided by A.R.C. The return consignment shall be insured and the costs arising hereof from shall be borne. A.R.C. will notify the customer of the return consignment opted for. Any changes as well as the change of the transporter or the type of dispatch may result in delays in transport and handling. Any other components covered by the warranty claim will be renewed by A.R.C. free of charge within the warranty period. We reserve the right to modify the design of the device – if necessary – thus increasing the safety or the functioning of the device. The responsibility for the design as well as any modifications of the device is exclusively incumbent on A.R.C. Laser GmbH. The customer will be informed about any changes which will be carried out on the premises of A.R.C. Laser GmbH

10.3 Sales and Service Information

For information about sales and service please contact:

A.R.C. Laser main office:

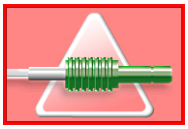
A.R.C. LASER GmbH
Bessemerstr. 14, D-90411 Nuremberg
Phone: +49 911 21779-0, Fax: +49 911 21779-99
Email: info@arclaser.de, www.arclaser.de

11 Symbols Description

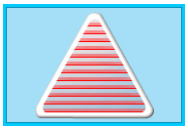
	Display brightness 5-100 %		Charging level of battery
	Aiming beam brightness 1-100 %		Temperature inside
	Aiming beam frequency (0-6Hz)		Sleep mode time
	Brightness Ready Button (5-100%)		Air humidity
	Tone (10-100%)		Pick language
	Pitch (5-100%)		State of power supply
	CW in “pulse on” field		Flash Drive inserted
	Single Pulse in “pulse off” field		State of wireless foot switch: Fully charged
	Your wireless footswitch is charged well		Please charge your wireless foot switch
	You have to charge your wireless foot switch		Cable version of foot switch is pre selected
	Settings, submenu		Home
	Next screen / Previous screen		Attention

11.1.1 **ERROR MESSAGES**

	State of charge of battery too low	Batteries need to be charged before continuing operation
	Door interlock missing	Connect the interlock plug included with the system
	Temperature too low	The environment is too cold for operating the laser

	Operating temperature too high	Please wait until laser cools down to reach a working temperature
	Air humidity too high	The laser should not be operated in this environment
	Fiber missing / or plugged incorrectly	Check fiber plug
	Ventilation fan blocked	Contact your A.R.C. Laser agent.

11.1.2 Warning Messages

	Change power supply
	Cooling element too hot
	Error ... Repeat
	Calibrated parameter is stored
	Detect Wireless Foot Switch (Double Click the wireless Foot Switch)
	Please wait

11.1.3 Status Report

The TFT-Display and Fiber-LED are getting dark and the green Status-LED starts to blink with 1 Hz	PowerSave Mode - Your FOX Laser lowers its power consumption. By pressing any button (despite of TouchScreen) you can resume to normal mode.

The TFT-Display, Fiber-LED, Status LED are dark	E-STOP button is pressed. Pull up E-STOP, and the device can be started.

12 Guidelines and Manufacturer's Declaration

12.1 Electromagnetic Emissions

The laser is intended for use in an environment as specified below. The customer or the user of the laser should ensure that it is used in such an environment.

Immunity tests	**Compliance**	**Electromagnetic environment – guideline**
RF emissions CISPR 11	Group 1/Class B	The laser uses RF energy exclusively for its internal function. Hence, RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1/Class B	The laser is suitable for use in any and all establishments including establishments in residential areas and those directly connected to the public power supply network which also supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

12.2 Electromagnetic Immunity (1)

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should ensure that it is used in such an environment.

Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	Complies with IEC 60601	Floors should be wood, concrete or ceramic tiles. Where floors are covered with synthetic material, the relative air humidity should be at least 30%.
Fast transient electrical /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	Not applicable ± 1 kV	The supply voltage quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	Not applicable	The supply voltage quality should be that of a typical commercial or hospital environment.

Immunity tests	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Voltage dips, short interruptions and variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for ½ cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	The supply voltage quality should be that of a typical commercial or hospital environment. When the user of the laser requires continued operation during power mains interruptions, it is recommended that the laser is powered from its battery or an uninterruptible power supply or an external battery.
Magnetic field with power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in mains frequency should be those of a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to the application of the test level.			

12.3 Electromagnetic Immunity (2)

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should ensure that it is used in such an environment.

Immunity tests	IEC 60601-test level	Compliance level	Electromagnetic environment – guidelines
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} (V_1) 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to the laser, including cables, than the recommended separation distance calculated for the equation applicable to the frequence of transmitter. **Recommended separation distance:** d = [1,17 : V_1] $\sqrt{P}$ d = [1,17 : E_1] $\sqrt{P}$ for 80 MHz to 800 MHz d = [2,33 m/V * vP for 800 MHz to 2,5 GHz where P maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer and *d is the* recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m (E_1) 80 MHz to 2,5 GHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with battery. To determine to electromagnetic environment resulting from the fixed RF transmitters, an electromagnetic site survey should be considered. Where the measured field strength in the location in which the laser is used exceeds the applicable RF compliance level indicated above, the laser should be observed to verify the normal operation. Where abnormal power is observed, additional measures may be necessary, such as reorienting or relocating the laser.

b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

12.4 Recommended Separation Distance between Portable and Mobile RF Telecommunications Equipment and the Laser

The laser is intended for use in an electromagnetic environment in which radiated RF are controlled. The customer or the user of the laser can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser as indicated below – according to the maximum output power of the communication equipment.

Maximum output power rating of the transmitter [W]	**Separation distance according to frequency of transmitter in meter [m]**		
	150 kHz to 80 MHz d = 1,17 1/V * vP	80 MHz to 800 MHz d = 1,17 1/V * vP	800 MHz to 2,5 GHz d = 2,33 m/V * vP
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,73
1	1,17	1,17	2,33
10	3,69	3,69	7,30
100	11,66	11,66	23,30

For transmitters with a maximum output power rating not listed above, the recommended separation distance d in meters (m) can be determined by using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer list.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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